

## Talmanco

Procedural steps taken and scientific information after the authorisation

| Application number | Scope                                                                                                                                                                                                                                                        | Opinion/ Notification <sup>1</sup> issued on | Commission Decision Issued <sup>2</sup> / amended on | Product Information affected <sup>3</sup> | Summary |
|--------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|------------------------------------------------------|-------------------------------------------|---------|
| IB/0016            | C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH | 06/11/2023                                   |                                                      | SmPC and PL                               |         |

<sup>1</sup> Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.

<sup>2</sup> A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.

<sup>3</sup> SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

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| IB/0015     | B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate | 11/09/2023 | n/a        |                              |                                                                                                                                                                                                                                                                        |
| IA/0014     | B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure                                                                                                 | 20/07/2022 | n/a        |                              |                                                                                                                                                                                                                                                                        |
| N/0013      | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)                                                                                                             | 09/06/2022 |            | PL                           |                                                                                                                                                                                                                                                                        |
| T/0012      | Transfer of Marketing Authorisation                                                                                                                                                                          | 13/10/2021 | 22/11/2021 | SmPC,<br>Labelling and<br>PL |                                                                                                                                                                                                                                                                        |
| R/0011      | Renewal of the marketing authorisation.                                                                                                                                                                      | 16/09/2021 | 09/11/2021 | SmPC,<br>Labelling and<br>PL | Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Talmanco in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity. |
| IA/0010     | A.7 - Administrative change - Deletion of manufacturing sites                                                                                                                                                | 26/03/2021 | n/a        |                              |                                                                                                                                                                                                                                                                        |
| IB/0009     | C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation                                                                                                               | 09/11/2020 | 09/11/2021 | SmPC and PL                  |                                                                                                                                                                                                                                                                        |
| IAIN/0008/G | This was an application for a group of variations.                                                                                                                                                           | 12/06/2020 | n/a        |                              |                                                                                                                                                                                                                                                                        |

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|           | <p>B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer</p> <p>B.III.1.a.3 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from a new manufacturer (replacement or addition)</p>                                                                                             |            |            |                 |  |
| IAIN/0007 | <p>B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing</p>                                                                                                                                                                                                                                                             | 11/12/2019 | 16/11/2020 | Annex II and PL |  |
| IAIN/0006 | <p>B.III.1.a.3 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from a new manufacturer (replacement or addition)</p>                                                                                                                                                                                                                                                                                                | 20/06/2019 | n/a        |                 |  |
| IA/0005/G | <p>This was an application for a group of variations.</p> <p>B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation</p> <p>B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer</p> <p>B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the</p> | 26/04/2019 | n/a        |                 |  |

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|             | relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |            |            |                              |  |
| N/0004      | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 11/03/2019 | 16/11/2020 | PL                           |  |
| IAIN/0003/G | <p>This was an application for a group of variations.</p> <p>B.II.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing</p> <p>B.II.b.4.b - Change in the batch size (including batch size ranges) of the finished product - Downscaling down to 10-fold</p>                                                                                                                                                                                                                                                                                                                                                                 | 17/11/2017 | n/a        |                              |  |
| IB/0002/G   | <p>This was an application for a group of variations.</p> <p>C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH</p> <p>C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH</p> <p>C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following</p> | 14/06/2017 | 19/02/2018 | SmPC,<br>Labelling and<br>PL |  |

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|           | assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH |            |            |                              |  |
| IAIN/0001 | A.2.a - Administrative change - Change in the (invented) name of the medicinal product for CAPs                                                               | 09/03/2017 | 19/02/2018 | SmPC,<br>Labelling and<br>PL |  |